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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,422	05/22/2000	Michel Schneider	1889-33	2399

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KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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05/28/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/576,422	Applicant(s) SCHNEIDER ET AL.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 22-34 and 39-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 22-34, 39-43, and 45-57 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/13/2008 has been entered.

Response to Amendment

Examiner acknowledges the reply filed 02/13/2008 in which claims 1-2, 5-6, 9, 22, 34, and 39-42 were amended and new claims 46-47 were added. Currently claims 1-9, 22-34 and 39-47 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 9, 22-23, 32, 39-43, and 46-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Trombley, III et al. (USPN6,575,930). Trombley, III et al. discloses an agitation device and dispensing system.

Regarding claims 1-6, 9, 22-23, 32, 39-43, and 46-47, Trombley, III et al. discloses a method and device capable of CT imaging organs, blood vessels or tissue of a mammal (cols 1-2) comprising administering to the mammal by injection or infusion a suspension of gas filled vesicle microparticles homogeneously (col 1, 35-67) distributed in an aqueous liquid carrier by means of an injector system comprising (Figure 1) a syringe (10) containing said suspension and a power driven piston (19) for injecting said suspension into a patient, said method comprising subjecting the suspension in the syringe to a rotation (circular barrel motion) or rocking motion carried out by a motor control system (stepwise back and forth motion of entire injector assembly) (Figures 4-5), thereby maintaining said suspension homogenous by preventing segregation of the microparticles by gravity or buoyancy, and without damaging said particles or disturbing their distribution, wherein said rotation or rocking

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motion is not caused by vibration produced by a motor unconnected to the syringe, and thereafter imaging the mammal (col 1, ln 10-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being obvious over Trombley, III et al. (USPN6,575,930) in view of Schneider et al (USPN5,686,060). Trombley, III et al. fails to explicitly disclose that the method is for suspension of the type of gas or composition of the surfactant and polymers.

Regarding claims 24-27, Schneider et al discloses a similar contrast solution injection method in which is disclosed a method for suspension of microparticles (col. 5 line 23), and that the gas is a halogenated gas CF₄, the gas is nitrogen (col. 6 line 60), the surfactant is a saturated phospholipids in a lamellar or laminar flow (col. 4 line 63).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Trombley, III et al. by incorporating the compositions as described by Schneider et al in order to create more stable microbubbles (col. 3, line 39).

Claim Rejections - 35 USC § 103

Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley, III et al. in view of Schneider et al. and further in view of Unger et al (USPN 6,028,066). The modified Trombley, III et al. discloses the method as described above but fails to explicitly disclose the fatty acid residue and the composition of the membrane.

Regarding claims 28-32, Unger et al discloses a similar method in which one of the phospholipids is a diacylphosphatidyl, the polymer of the membrane is selected from polyglycolic acid, the material envelope of the microballoon is made from albumin, bounded by saturated triglycerides (cols 1-2).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of the modified Trombley, III et al. by incorporating the compositions as taught by Unger et al in order to increase the signal received from micobubbles and decrease background tissue signals.

Claim Rejections - 35 USC § 103

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley III, et al. in view of Schneider et al. in further view of Unger ('066) and further in view of Unger (USPN5,334,381).

The modified Trombley, III et al. discloses the method as described above but fails to disclose that the liposomes are filled with an iodinated compound.

Regarding claim 33, Unger ('381) discloses a similar method in which the liposomes are filled with an iodinated compound (col. 8 line 21).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of the modified Trombley, III et al. by incorporating the compositions as taught by Unger ('381) in order to better detect tumors in the liver (col. 8 line 21).

Claim Rejections - 35 USC § 103

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley, III et al. in view of Schneider et al. in further view of Unger ('066) in further view of Unger ('381) and further in view of Minchey et al. (USPN5,415,867).

The modified Trombley, III et al. discloses the method as described above but fails to disclose that the iodine over lipid ratio is 3 or more.

Minchey discloses a similar method in which the iodine over lipid ratio is 3 or more (see table 1).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of the modified Trombley, III et al. by incorporating the compositions as taught by Minchey in order for better contrast agent detection.

Claim Rejections - 35 USC § 103

Claims 7-8 are rejected under 35 U.S.C 103(a) as being unpatentable over Trombley, III et al. (USPN6,575,930). Trombley et al. meets the claim limitations as described above except for the specific rotation speed and rotation direction.

Regarding claims 7-8, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use different rotational speeds and direction depending on the contrast agent type and relative size in order to maintain a homogenous suspension as taught by Trombley, III et al. and since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233 (CCPA 1955).

Allowable Subject Matter

Claim 44 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-9, 22-34, 39-43, and 45-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 05/20/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763